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**OFFICE OF PETITIONS**

NOVARTIS INSTITUTES FOR  
BIOMEDICAL RESEARCH, INC.  
220 MASSACHUSETTS AVENUE  
CAMBRIDGE MA 02139

In re Application of :  
Bollbuck, et al. :  
Application No. 10/532,331 : ON APPLICATION FOR  
Filed: April 22, 2005 : PATENT TERM ADJUSTMENT  
Atty Docket No. PA/4-32743A :

This is in response to the "PETITION REGARDING PATENT TERM ADJUSTMENT UNDER C.F.R. § 1.705(b)" filed August 24, 2009. Applicants request that the determination of patent term adjustment be corrected from six hundred twenty-nine (629) days to nine hundred forty-eight (948) days. Applicants request this correction, in part, on the basis that the Office will take in excess of three years to issue this patent and in light of the recent court decision in Wyeth v. Dudas, No. 07-1492 (D.D.C. September 30, 2008).

As the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.705(b) is **DISMISSED as PREMATURE**.

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.702(b). (This is true even where a request for continued examination (RCE) was filed). The computer will not undertake the § 1.702(b) calculation until the actual date of issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under § 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As

such, the Office can not make a determination on the correctness of the patent term adjustment until the patent has issued.

Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, applicant is advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent. However, as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, applicant must timely file an application for patent term adjustment prior to the payment of the issue fee<sup>1</sup>.

Further review of the application file history reveals that the Office noted a period of delay of 638 days, pursuant to 37 CFR 1.702(a)(1), for the Office failing to mail at least one notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C.

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<sup>1</sup> For example, if applicant disputes both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then applicant must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the 37 CFR 1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.

371 in an international application.<sup>2</sup> Applicants indicate, however, the period of adjustment to the patent term pursuant to 37 CFR 1.702(a)(1) is 641 days. As stated in 37 CFR 1.703(a)(1), the period of adjustment under § 1.702(a) is the number of days in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements under 35 U.S.C. 371 and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first. Accordingly, June 26, 2006, is the date that should be used to calculate the examination delay under 37 CFR 1.703(a).

Pursuant to 37 CFR 1.703(a)(1), the period of adjustment under 37 CFR 1.702(a) is 638 days, counting the number of days beginning on the day after the date that is fourteen months after the date on which the application fulfilled the requirements under 35 U.S.C. 371, June 26, 2006, and ending on the date of mailing of the non-final Office action, March 24, 2008.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Any request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 CFR 1.705(d) and must include payment of the required fee under 37 CFR 1.18(e).

The application is being forwarded to the Office of Data Management for issuance of the patent. The patent term adjustment indicated on the patent (as shown on the Issue

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<sup>2</sup> 37 CFR 1.702, provides grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

(a) Failure to take certain actions within specified time frames. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to:

(1) Mail at least one notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 in an international application;

Notification mailed about three weeks prior to the patent issuance) will include any additional adjustment accrued both for Office delay in issuing the patent more than four months after payment of the issue fee and satisfaction of all outstanding requirements, and for the Office taking in excess of three years to issue the patent (to the extent that the three-year period does not overlap with periods already accorded).

Telephone inquiries specific to this decision should be directed to Kenya A. McLaughlin, Petitions Attorney, at (571) 272-3222.

A handwritten signature in cursive script that reads "C. P. Donnell".

Christina Tartera Donnell  
Senior Petitions Attorney  
Office of Petitions